

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

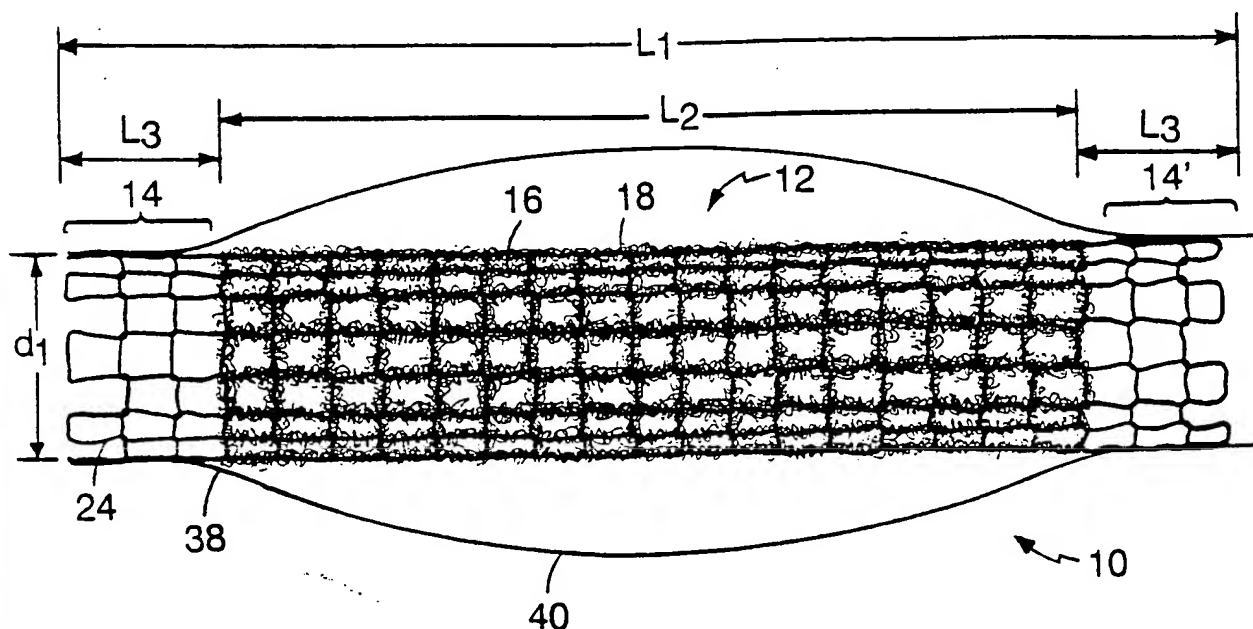
**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>5</sup> :</b> A61F 2/04, 2/06, A61M 29/00 A61M 29/02	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 94/01056</b>  <b>(43) International Publication Date:</b> 20 January 1994 (20.01.94)
<b>(21) International Application Number:</b> PCT/US93/06529 <b>(22) International Filing Date:</b> 12 July 1993 (12.07.93)  <b>(30) Priority data:</b> 07/912,902                      13 July 1992 (13.07.92)                      US  <b>(71) Applicant:</b> BOSTON SCIENTIFIC CORPORATION [US/US]; 480 Pleasant Street, Watertown, MA 02172 (US).  <b>(72) Inventors:</b> ANDERSEN, Erik ; Ronnens Kvarter 5, Osted, DK-4000 Roskilde (DK). STRECKER, Ernst, Peter ; Vierordtstrasse 7a, D-7500 Karlsruhe 41 (DE).  <b>(74) Agent:</b> WILLIAMS, John, N.; Fish & Richardson, 225 Franklin Street, Boston, MA 02110-2804 (US).		<b>(81) Designated States:</b> CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** TUBULAR MEDICAL PROSTHESIS**(57) Abstract**

A tubular prosthesis (10) including a tubular wall portion (12) of loosely interlocked pattern, e.g. of knitted loops, constructed to function within a body lumen. The loops are preferably formed of co-knitted strand materials. A first strand material (16) is a metal strand that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen. A second strand material (18) is a predetermined substance selected to provide desired characteristics to the wall of the prosthesis.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LU	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 5    A61B17/11    A61F2/06    A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC:

### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 5 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 303 767 (WALSH MANUFACTURING LTD.) 22 February 1989	1,5
Y	see page 4, line 23 - line 29; figure 2	2-4,9
A	see page 9, line 34 - line 40; table 1 ---	6,7
Y	WO,A,80 01460 (AB TESI) 24 July 1980	2,3,9,20
A	see page 3, line 24 - line 29; figures ---	17,18
Y	US,A,3 254 651 (COLLITO) 7 June 1966 see the whole document ---	4,10-16
Y	US,A,4 086 665 (POIRIER) 2 May 1978 see abstract; figures 1,2 ---	10-16
X	US,A,2 453 056 (ZACK) 2 November 1948	19
Y	see page 2, line 24 - page 3, line 59; figures ---	20-23
	---	

-/--

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

6 December 1993

Date of mailing of the international search report

08. 12. 93

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 cpo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Sanchez y Sanchez,J

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,4 352 358 (ANGELCHIK) 5 October 1982 see column 3, line 60-68; figures 1-4 ---	21-23
A	US,A,5 089 014 (HOLFER) 18 February 1992 see column 4, line 4 - line 53; figures 2-5 ---	25
X	US,A,4 247 292 (ANGELL) 27 January 1981 see column 3, line 42 - line 44; figures 1-3 ---	26,27 28
Y	WO,A,89 02254 (TAHERI) 23 March 1989 see abstract; figures 3,5-7 ---	28
Y	WO,A,90 14804 (BAXTER INTERNATIONAL) 13 December 1990 see page 24, line 15 - page 25, line 12; figures 8-11 ---	26,27
Y	US,A,4 340 977 (BROWNLEE ET AL.) 27 July 1982 ---	26,27
A	US,A,2 127 903 (BOWEN) 23 August 1938 ---	
A	US,A,3 254 650 (COLLITO) 7 June 1966 ---	
A	US,A,4 728 328 (HUGHES ET AL.) 1 March 1988 -----	

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 93/03517

**Box I** Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II** Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

For further information see Form PCT/ISA/206 sent on 26.08.93.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0303767	22-02-89	US-A- 4657019	14-04-87
		CA-A- 1261706	26-09-89
		CA-A- 1277197	04-12-90
		EP-A- 0158316	16-10-85
		US-A- 4873975	17-10-89
		US-A- 4917087	17-04-90
		US-A- 4771775	20-09-88
		US-A- 4787386	29-11-88
-----			
WO-A-8001460	24-07-80	SE-C- 424045	07-10-82
		DE-C- 3028512	21-11-91
		EP-A, B 0023208	04-02-81
		GB-A, B 2049437	31-12-80
		JP-B- 5005481	22-01-93
		JP-T- 56500038	16-01-81
		SE-B- 423045	13-04-82
		SE-A- 7900282	13-07-80
		US-A- 4434797	06-03-84
-----			
US-A-3254651		NONE	
-----			
US-A-4086665	02-05-78	NONE	
-----			
US-A-2453056		NONE	
-----			
US-A-4352358	05-10-82	NONE	
-----			
US-A-5089014	18-02-92	NONE	
-----			
US-A-4247292	27-01-81	NONE	
-----			
WO-A-8902254	23-03-89	US-A- 4851001	25-07-89
		EP-A- 0331721	13-09-89
		JP-T- 2501042	12-04-90
		JP-B- 5007025	27-01-93
-----			
WO-A-9014804	13-12-90	EP-A- 0474748	18-03-92
		JP-T- 4505866	15-10-92
-----			
US-A-4340977	27-07-82	NONE	



Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-2127903		NONE	
US-A-3254650		NONE	
US-A-4728328	01-03-88	NONE	



- 1 -

**TUBULAR MEDICAL PROSTHESIS**Field of the Invention

This invention relates to tubular prostheses which  
5 are placed within the body.

Background of the Invention

Tubular prostheses are used in body lumens to perform various functions. For example, a tubular stent may be used to maintain the opening of an esophagus that  
10 has been restricted by a tumor or a blood vessel restricted by plaque. Tubular grafts are used to substitute for or reinforce a weakened lumen, such as the aorta or other blood vessel that has been weakened by an aneurysm. In this latter technique, a graft of a knitted  
15 dacron may be used to advantage since the textured nature of the textile can induce blood clotting along the graft to contribute to the patency of the lumen formed by the graft.

Tubular prostheses for purposes such as the above  
20 may be positioned in the body lumen during a surgical procedure or may be delivered into the body by a catheter that supports the prosthesis in a compact form during percutaneous insertion and transport through body passageways to a desired site. Upon reaching the site,  
25 the prosthesis is expanded so that it engages the walls of the lumen. After this operation, the catheter is removed, leaving the device in the body.

The expansion technique may involve forcing the prosthesis to expand radially outwardly, for example, by  
30 inflation of a balloon carried by the catheter. Knitted, balloon expandable stents are discussed for example in Strecker U.S. 4,922,905, the entire content of which we hereby incorporate by reference. In another technique, the prosthesis is formed of an elastic material that can  
35 be arranged and held in a compact form for insertion and

- 2 -

allowed to expand when in position by its own internal elastic restoring force. Knitted self-expanding stents are described in Strecker PCT EP 91/02194 and in Anderson U.S. Serial No. 07/773,847, filed October 9, 1991, the  
5 entire contents of both applications being incorporated herein by reference.

#### Summary of the Invention

The invention provides prostheses with improved properties by forming the prostheses of multiple  
10 filaments or strands of different materials, one of which is a structural filament, preferably metal. In preferred embodiments, the strands are knit into a tubular form. In some embodiments, multiple strands of different materials are co-knit into a stent. The term "co-knit"  
15 as used herein refers to the knitting of multiple discrete strands in the knit pattern. In certain preferred embodiments, the strands are in a parallel co-knit form, by which is meant the strands of the various substances lie in parallel in all contiguous loops of the  
20 co-knit portion of the knit pattern. In other embodiments, the multiple strands of different materials are alternately knit such that adjacent rows of knit loops are of the different materials. In some embodiments, different regions of the prosthesis are  
25 formed of different sets of materials. In still further embodiments, a tubular structure of a first knit material is provided as a sheath over a second tubular structure of another knit material.

In one particular aspect, the invention features a  
-----30 tubular prosthesis having a tubular wall portion of loosely interlocked knitted loops constructed to function within a body lumen. The loops are formed of co-knitted strand materials where a first strand material of the loops is a metal wire that structurally defines the  
35 tubular shape of the prosthesis and maintains the shape

- 3 -

when positioned in the lumen and a second strand material of the loops is co-knitted with the metallic strand and is formed of a predetermined substance selected to provide desired characteristics to the wall of the  
5 prosthesis.

In another particular aspect, the invention features a vascular graft prosthesis for bridging an aneurysm in an arterial lumen of the body. The graft has a tubular wall portion of loosely interlocked knitted  
10 loops constructed to function within the arterial lumen. The loops are formed of co-knitted strand materials where a first strand material of the loops is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and  
15 a second strand material of the loops, co-knitted with the metallic strand, is formed of a predetermined non-metallic substance selected to provide desired characteristics to the wall of the prosthesis to enable it to perform its the function to effectively provide a  
20 patent covering over the structure of the graft.

In another particular aspect, the invention features a vascular prosthesis for use in an arterial lumen of the body. The prosthesis has a tubular wall portion of loosely interlocked knitted loops constructed  
25 to function within the arterial lumen. The loops are formed of parallel co-knitted strand materials where a first strand material of the loops is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and  
30 a second strand material of the loops, co-knitted with the metallic strand, is a textured textile strand substance selected to enhance patency characteristics of the wall of the prosthesis.

In another particular aspect, the invention  
35 features a tubular prosthesis. The prosthesis has a

- 4 -

tubular wall portion of loosely interlocked knitted loops constructed to function within a body lumen. The loops are formed of multiple strand materials where a first strand material of the loops is a metal wire that

5 structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and a second strand material of knitted loops is formed of a predetermined substance selected to provide desired characteristics to the wall of the prosthesis.

10 In yet another particular aspect, the invention features a tubular prosthesis. The prosthesis has a tubular wall portion of a loosely interlocked regular pattern of strands constructed to function within a body lumen. The pattern is formed of multiple strand

15 materials where a first strand material of the pattern is a metal wire that structurally defines the tubular shape of the prosthesis and maintains the shape when positioned in the lumen and a second strand material of the pattern, integrated with the metallic strand as part of the

20 pattern, is formed of a predetermined substance selected to provide desired characteristics to the wall of the prosthesis.

The features of the above aspects can be combined. In addition, various embodiments may include one or more

25 of the following features. The prosthesis has an anchoring end portion of knitted loops which are knitted integrally with at least a portion of the co-knitted wall portion and formed of a strand material adapted to make contact with the wall of the body lumen to maintain the

---

30 axial position of the prosthesis in the body lumen. The anchoring end portion is formed of contiguous loops of the first, metal strand material joined integrally with the the wall portion that includes the co-knit second strand. The anchoring end portion of the prosthesis is

35 self-expanding and is formed of elastic metal strand

- 5 -

capable of being reduced in radial size without plastic deformation and retaining self-restoring capability such that the end portion can be reduced to a relatively small size for introduction lengthwise into the lumen, and when  
5 freed can radially self-expand to tubular form to engage the wall of the lumen. The anchoring end portion is formed of the plastically deformable metal and is knit integrally with the wall portion. The anchoring end portion is formed of metal strand flared to a diameter  
10 greater than the wall portion. The prosthesis has an anchoring portion at each of its axial ends. The wall portion is expandable to desired size by means of an internal expanding force or is self-expanding. The first strand material of the wall portion is a plastically  
15 deformable metal and the wall portion is expandable to a desired size by application of an internal expanding force. The first strand is selected from tantalum and nitinol. The second strand is selected from dacron, wool, nylon, polyethylene and teflon. The material of  
20 the second strand is textured to induce blood clotting. The prosthesis is sized for use as an aortic graft having, for example a porosity of about 4000 ml/min or more at implantation. The second strand is formed of a body fluid-dissolvable suture material. The second  
25 strand is an absorbing member that includes a drug. The second strand material is a metal, such as a dense metal that enhances the radiopacity of the prosthesis. The co-knit strands are in a parallel co-knit pattern. The first strand material and second strand material are  
30 continuously, single knitted to form regions of the tubular knit structure formed of the first material and regions of the knit structure formed of the second material. The first and second strand materials are alternately knitted to form successive alternating loop  
35 rows of the first and second material. The first and

- 6 -

second strand materials are formed as separate knitted loop tubular structures and the second strand knitted loop structure extends coaxially with the first strand knitted loop structure and extends over an end of the first strand knitted loop structure to form a cuff to secure the first knitted structure to the second knitted structure. Rather than knitting, the tubular prosthesis pattern is formed by co-weaving or co-crocheting the strands, such as into a pattern formed of multiple parallel strands.

The invention also includes methods for manufacture and use of the prostheses described. Still other aspects of the invention will be understood from the following description and from the claims.

Description of the Preferred Embodiment

We first briefly describe the drawings.

Drawings

Fig. 1 is a side view, in magnified scale, of an aortic graft prosthesis according to the invention using two different strand materials co-knit into a tubular structure in parallel co-knit fashion, while Fig. 1a is a greatly expanded view of adjacent loops in the wall portion of the graft of Fig. 1;

Fig. 2 is a side view of another prosthesis according to the invention;

Fig. 3 is a side view of another prosthesis according to the invention, while Fig. 3a is an enlarged view of a portion of the prosthesis of Fig. 3;

Fig. 4 is a side view of another prosthesis according to the invention;

Fig. 5 is a side view of another prosthesis according to the invention; Fig. 5a is an end view taken at line aa of Fig. 5; Fig. 5b is a cross-section view taken at line bb of Fig. 5; and Fig. 5c is an enlarged side view of the prosthesis of Fig. 5.



- 7 -

Fig. 6 is a diagrammatic view of a circular knitting machine configured for alternate knitting while Figs. 6a-6d illustrate the operation of a needle used in a circular knitting machine and Fig. 6e illustrates a circular knitting machine configured for parallel co-knitting.

Figs. 7-7d illustrate schematically, on a reduced scale, placement of an embodiment of an aortic graft prosthesis in the body.

#### 10 Description

Referring to Figs. 1 and 1a, an embodiment of a prosthesis according to the invention is a graft 10 which may be positioned in the abdominal aorta 38 within an aneurysm 40. The graft 10, of overall length  $L_1$ , e.g., about 8 cm, includes a wall portion 12, of length  $L_2$ , e.g., about 5 cm, that spans the aneurysm 40 and anchoring end portions 14, 14', each of length  $L_3$ , e.g., about 1.5 cm, that engage healthy portions of the aorta to anchor the prosthesis in the lumen. As illustrated, the graft 10 is formed of loosely interlocked knitted loops of material. The diameter  $d_1$  of the graft 10 and the respective lengths are variable, as discussed below, to accommodate various aorta diameters and aneurysm conditions. For example, the diameters may be in the range of 10-20 mm and prosthesis lengths  $L_1$  in the range of about 4-8 cm.

Referring particularly to Fig. 1a, in the wall portion 12, the loops are formed by parallel co-knitting of a first strand material 16, a metal, and a second strand material 18, preferably of texturized filament or fiber. The first strand material substantially defines the tubular structure of the graft and is a selected metal strand of wire such as tantalum. The second strand material 18 is preferably non-metallic, e.g. a polymer or natural textile fiber or the like, such as a textile

- 8 -

yarn, selected to provide a desired characteristic of the prosthesis to enable it to perform a desired function. In the case of an aortic graft, the second material is selected for its capability of inducing the clotting of blood. In these embodiments, the second strand material 18 is preferably a texturized material such as dacron yarn formed of crimped or texturized multiple monofilaments, typically in excess of about 20, with multiple, randomly extending segments 22 that extend into the open area 25 between adjacent knitted loops.

The anchoring portions 14, 14' are formed of wire knitted strand 24, that does not include a co-knit strand. Strand 24 is integral with the wall portion 12 and may be a knitted extension of the metal strand material 16. (Alternately, the anchoring end portions may be a co-knit structure which may be the same or different from the co-knit structure of the central wall portion.)

A particular aspect of this embodiment is parallel co-knitting to form rather loosely interlocked loops with selected, loop length,  $L_4$ , e.g. about 1.8 mm that provides substantial open area 25. This design facilitates wrapping the prosthesis into small size for delivery intralumenally. Wrapping produces a sliding action of adjacent loops within the open area that avoids stress concentrations in the wires, yet the size of the open area and texturized nature and number of strands formed of the second material provides strand components that extend within the open areas of the loops. By suitable selection, these components can be sufficient to produce clotting in a sufficiently short time that excessive bleeding through the graft will not occur when the graft is placed inside the lumen. A particular benefit of this design is that, generally, the graft need not be pre-clotted before placement. Over time in the

- 9 -

body, the graft accepts cells, endothelializes and becomes a patent portion of the artery. The porosity of the graft may be, e.g., about 4000 ml/min or more at implantation. This degree of porosity facilitates  
5 migration of cells (e.g. fibroblasts and endothelial cells) into and through the knit structure such that cellular structure can be formed. (Graft porosity as measured by water filtration testing is discussed, for example, in Wesolowski, S.A. Dennis, C., Fundamentals of  
10 Vascular Grafting, New York, McGraw-Hill, 1963.)

Further, the loosely interlocked loops formed by the co-knitting process of metal wire and the other selected substance are free to slide with respect to each other while in use in the body. This ability for the  
15 loops to slide enhances the ability of the device to maintain its axial working length and resist migration when the prosthesis is locally radially compressed. Under such compression the loop structure may locally lengthen or shorten to accommodate similar changes in the  
20 vessel in which it is installed, as may occur for instance if the aorta is stretched. The loosely co-knitted structure also allows the graft to negotiate tortuous vasculature during delivery on a catheter because of its flexibility longitudinally.

25 The co-knitting has other advantages as well. For instance, it provides a mechanism for attachment of multiple strand materials without need for additional means such as tie strands and the like, although these optionally may be employed.

30 One embodiment of a graft as in Fig. 1 and 1a employs, in parallel with the metal strand, four parallel strands of dacron (44DTEX), each strand consisting of 27 filaments, full drawn R02 medical grade (available from E.I. DuPont de Nemours and Co., Wilmington, DE). Before  
35 co-knitting, the strands are texturized by false twisting

- 10 -

and set by radiation heating. Parallel co-knitting with a tantalum wire strand (0.10 mm) is carried out to produce a 10 mm diameter ( $d_1$ ) graft with a circumferential loop count of 12 loops and a wall portion of 4 cm length ( $L_2$ ) consisting of 29 co-knit rows and anchoring end portions, of 10 single knit rows of tantalum. The loop length of the knitted loops in the axial direction is about 1.8 mm.

#### Other Embodiments

- 10 Generally, the principle of combining different strands to form a prosthesis provides a ready ability to adapt the properties of the stent to suit various applications, the respective strands being selected to provide properties which enhance performance. In
- 15 general, at least one of the strands will be selected for its structural properties to enable the stent to maintain an open passage. In many preferred embodiments such strands are of selected metal. The metal strand material may be of a metal selected to enhance radiographic
- 20 visualization of the prosthesis during the delivery through a body lumen, the positioning at a desired site and the assessing of the efficacy of treatment. Particular advantages are achieved when the metal strand is formed of a highly radiopaque metal such as tantalum.
- 25 The metal strand material also may be selected for features relating to its expandability, to enable a single size-prosthesis to be manufactured for use in lumens of somewhat varying size as may be encountered from patient to patient. The metal strand material may
- 30 be a metal capable of yielding when the stent is expanded in the lumen by an internal radial force, such as by balloon expansion. Such a prosthesis is therefore size-selectable for the desired application. In other cases, the metal strand material is selected to form an
- 35 elastically self-expanding prosthesis which may be

- 11 -

reduced to a small diameter for introduction into the body and allowed to expand at a desired site by release of a restraint. Embodiments in this case would use an elastic metal strand such as nitinol wire, which also can  
5 enhance maintenance of the elasticity of the vessel in which it is placed and can be used to widen an occluded vessel. For example, the prosthesis may be used as a stent in the biliary duct or the esophagus to widen these ducts in the cases where they have been occluded by  
10 tumors. In the case of stents formed by co-knitting another strand with a self-expanding elastic metal, the co-knit portions may still require balloon expansion because of the restraining effect of the second strand, or to ensure good seating. The metal strand may also  
15 comprise a two component cored material as discussed in USSN 07/861,253, filed March 31, 1992, the entire contents of which are hereby incorporated by reference.

The second strand material may be a wool, nylon, polyester, polyethylene or teflon, selected e.g. for the  
20 degree of texture desired. Various embodiments may also include a strand adapted for drug delivery. The second strand material may also be a dissolvable suture material or an absorbent such as hollow absorbent material carrying drug that inhibits body rejection of the  
25 prosthesis or inhibits hyperplasia. The drug may be slowly releasable as the strand dissolves, finally leaving only the thin metal first strand to provide desired reinforcing structure through the loops of which healthy endothelial tissue can gradually grow without the  
30 chaffing or grinding effects that might occur at points of intersection of the strands that have dissolved. In other embodiments, both the first and second strands are metals that provide different desirable properties. For example, one strand may be an elastic material such as  
35 nitinol and the second strand a dense radiopaque strand

- 12 -

such as tantalum that enhances the fluoroscopic visibility of the device. Preferably, in these latter embodiments, one or both of the metal strands include a polymer coating to avoid electrolytic corrosion induced by contact of dissimilar metals in an aqueous body fluid environment. The coating may be selected to be dissolvable. A drug may be incorporated in the coating so that, by the dissolving action, the drug is released over time. The rate of dissolution of a coating may be selected so that removal of the coating occurs at a desired time, to enable electrolytic corrosion to dissolve one of the strands, thereby to reduce the amount of metal remaining in the body. The coating may also be seeded with fibrin on the surface to control a fibrin layer with the aim of forming neuro intima. A strand material employing a semipermeable membrane for drug delivery can also be used. One such material is described in EP 0441516, published August 8, 1991, the entire contents of which is hereby incorporated by reference.

Different portions of a prosthesis can be tailored with specific, different properties, to achieve different functions, by using various strands of different materials at different locations, which are easily implemented during the knitting process. As illustrated above in Figs. 1 and 1a, the anchoring portions 14, 14' can be, for example, axial knitted extensions of the metal strand material 16 which may be produced by ceasing co-knitting of the second strand material at a desired point in production. In some cases a second metal strand which can be of the same or different properties from the first metal can be added in this region to strengthen the anchoring portions or for other purposes.

In certain cases of an aortic graft, as discussed above with respect to Figs. 1 and 1a, it is particularly

- 13 -

advantageous not to have clot-producing strands in the anchoring region so that substantial clotting will not be induced at the end portions where it is not necessary and the mechanical properties of the metal strand can perform  
5 their function unimpeded to provide secure anchorage. The strands at the end portions may be selected to be elastic, self-expanding, or plastically deformable.

Alternatively, the metal strand at the anchoring ends may be a different strand material than either the  
10 first strand material or second strand material in the main body or wall portion of the stent, to produce a desired effect, such as self-expandability in the anchoring ends and balloon expandability in the wall portion. The anchoring end material can be co-knit to  
15 overlap with a portion of the wall portion.

Referring to Fig. 2, a prosthesis 26 is illustrated having a wall portion 12 and anchoring ends 28, 28'. In this embodiment ends 28, 28' are flared outwardly to a diameter,  $d_2$ , such that they impress upon  
20 the inner wall of a body lumen 2 for anchoring the prosthesis 26 in place. As with the embodiments above, the strands 25 at the anchoring ends may be selected to make the ends self-expanding or expanded by plastic deformation by an internal expansion device.

25 Referring to Figs. 3 and 3a, in another embodiment, rather than parallel co-knitting, a stent 50 may be formed by continuous knitting a first strand material 52 and a second strand material 54 in an alternating, sequential co-knit fashion to form adjacent  
30 spiral patterns of loops along the length of the stent, resulting in successive alternating rows of different material in a single knit structure. In preferred embodiments, strand 52 is a metal strand, most preferably tantalum, and second strand 54 is a dissolvable,  
35 resorbable thread of material such as is used in

- 14 -

dissolvable sutures. In a predetermined time, in the body, the thread strand 54 is dissolved leaving only circumferential rings of successive loops of metal which avoids strand intersections that could exert shearing forces or other damaging effects on surrounding and growing tissue. In preferred embodiments, drugs e.g., an antiproliferative, can be embedded in the dissolvable strand to gradually deliver the drug to surrounding tissue as the strand dissolves. In an alternative preferred embodiment, the first strand is a metal selected for its elastic properties and the second strand is a radiopaque metal, with one or both of the metals including a coating to inhibit, at least temporarily, the electrolytic degradation of the strands, as mentioned above.

Referring to Fig. 4, in another embodiment, rather than parallel co-knitting, stent 60 is formed by continuous knitting of a first strand 62, preferably a metal such as tantalum and a second strand 64 such as dacron in alternating regions, to perform specific functions. Metal strand 62 in the end regions provide anchoring portions while textile strand 64 provides a patent graft region.

Referring to Figs. 5-5c, in another embodiment, rather than parallel co-knitting, a graft 70 is provided that is formed of a first, separately knitted tubular structure 72 formed of a first strand 73, e.g. tantalum, and a second separately tubular knitted structure 74, assembled coaxially within the first structure 72 and formed of a second strand 75, e.g. dacron. At the ends 76, 76', the second tubular knit structure 74 is rolled over the outside of the first knit structure to form a cuff, to secure the assembly together. The first and second tubular knit structures may also be secured by sewing them together. In an alternative construction,



- 15 -

the second tubular knitted structure of dacron could be a continuously co-knitted extension of the first metal tubular structure and the dacron knitted structure is pulled through the center of the metal structure. In  
5 other embodiments, the fabric knitted structure is on the outside of the metal knitted structure or is sandwiched between two metal structures or the metal knitted structure is between two fabric knitted structures. In another embodiment two tubular members can be effectively  
10 formed as a double knit structure.

In the embodiments of the invention discussed in the above description, the prostheses are formed of knitted strands, in other embodiments, other methods of forming a tubular structure from strands such as co-  
15 weaving, co-crocheting and the like can also be used. In some cases, with knitted embodiments or otherwise, it may be desirable to use a velour which is a variant of knitted material in which loops of yarn extend outward from the surface of the fabric formed by the knit  
20 structure.

#### Manufacture

Tubular prostheses of the invention may be manufactured on a circular knitting apparatus. Referring to Figs. 6-6e, knitting apparatus are diagrammatically  
25 shown. Referring to Fig. 6, the apparatus includes a knitting head 92 for guiding a series of needles 94, 94' which are axially extended and retracted by a rotating (arrow 95) contoured platen 96. Spools 98, 98' feed strand material to the needles during the knitting  
30 operation. The knit structure 101 is produced around a plastic mandrel 100 which is drawn downward in the direction of arrow 102.

Referring particularly to Figs. 6a-6d, the needles, such as needle 94, include a needle head 106 and  
35 a pivoted needle tongue 108. During the upstroke of the

- 16 -

needle, the head 106 grasps a feed from the strand spool 98, the tongue 108 being initially in the downward position (Fig. 6a). On the downstroke, the tongue 108 is deflected upward as it engages the portion of the  
5 knitting head 94, thus enclosing the strand within the head (Fig. 6b). The downstroke continues for a selected length within the knitting head (Fig. 6c). On the upstroke, the strand deflects the tongue 108 downward, thus releasing the strand from the needle head 106 (Fig.  
10 6d). The cycle is repeated as the platen 96 rotates.

The contour of the platen is selected to drive the needles for forming a desired knit pattern. In the embodiment in Fig. 6, needles 94, 94' disposed about the needle head 92 at 180° are synchronized to simultaneously  
15 pass through the stroke cycle by platen 96 which is contoured symmetrically with opposed raised sections 99, 99' and intervening valleys. By providing different strands on spools 98, 98', the knit pattern will be a continuous alternating tubular knit structure 101 such as  
20 that described with respect to Fig. 3, above.

For forming parallel co-knit structures, multiple strands are passed through each needle head to cause simultaneous parallel co-knitting. Referring to Fig. 6e, the circular knitting machine is shown configured for  
25 parallel co-knitting by providing strands from spools 110, 110', 112, 112' so that needles 94, 94' are provided simultaneously with multiple strands of different materials. A platen 118 is provided which has a single raised section 120 to sequentially drive each needle  
30 about the periphery of the knitting head through the stroke cycle. The parallel co-knit structure 103 is formed on mandrel 100. Co-knitting may be ceased by providing only a single strand to the needle heads, for example when knitting a graft such as in Fig. 1, with a

- 17 -

co-knit wall portion and integral single knit anchoring end portions.

Generally, the number of needles circumferentially disposed around the knitting head determines the number of circumferential knit loops. The size of the needle affects the narrowness of the loops; a smaller needle forms a narrower loop since the strand bends more acutely around the narrower needle head. The diameter of the knitting head affects the diameter of the knitted stent.

10 Delivery

The prostheses of the invention can be positioned by various means. For example, for a balloon expandable graft with balloon expandable anchoring end portions, the graft may be positioned using a catheter with a balloon having a length substantially the length of the graft and an inflated diameter sufficient to expand the graft to the desired maximum size and to smaller sizes by partial inflation. For a graft which has a self-expanding wall portion and self-expanding anchoring ends, the graft can be restrained to small size on a catheter with a constraint such as a sleeve which is removed to release the stent at the placement site. These self-expanding grafts may be wrapped around a distal portion of the catheter in a 'jelly roll' fashion.

Referring to Figs. 7-7d, positioning of a graft having self-expanding anchoring ends and a balloon expandable wall portion is illustrated. The graft 80 is positioned at the distal end of a catheter 30 which includes an inflatable balloon 32 upon which the graft is placed and an axially slidable sleeve member 34 which is placed over the graft 80 to constrain the self-expanding anchoring ends 82, 82' and a balloon wall portion formed of a co-knit tubular structure including a clot-inducing strand and a metal strand. The catheter 30, which for introduction through a vessel such as the iliac artery 36

- 18 -

has a diameter of about 20 French; is advanced to the aorta 38 that has been weakened by an aneurysm 40. The catheter 30 positions the graft such that graft 80 spans the region effected by aneurysm 40 and axially therebeyond to portions 42, 44 of the aorta that remain healthy but such that the graft will not interfere with the renal arteries 41. In case of an approach through the femoral artery a smaller catheter (about 12 F) is used. In this latter case, the stent is constructed with a 5 to 1 ratio of expanded to compressed size. Placement of the graft should be accurate to within about  $\pm 0.5$  cm to properly position the anchoring ends 80, 80' which are typically about 1.5 cm in length on the healthy portions of the aorta.

Referring to Fig. 7a, the graft 80 is placed in the lumen by withdrawing the sleeve 34 axially (arrow 46) which releases the restraint on end portion 82' causing it to expand to engage the inner wall of the healthy portion 44 of the aorta.

Referring to Fig. 7b, with sleeve 34 completely removed from the prosthesis the anchoring end 82 similarly expands to engage the healthy portion 42 of the aorta, thus fixing the prosthesis in the lumen and positioning the wall portion 84, which remains unexpanded, at the location of the aneurysm 40.

Referring to Fig. 7c, a view in partial cross section, the balloon 32 is inflated to produce a radial force (arrow 48) which expands the wall portion 84 to a desired diameter that approximates the diameter of the healthy portions of the aorta such that the wall portion of the graft does not engage the weakened tissue of the aneurysm.

Referring to Fig. 7d, after expansion of the wall portion 84, the balloon 32 can be deflated and the catheter removed from the lumen, leaving the prosthesis

- 19 -

80 positioned across the aneurysm and securely anchored.  
As discussed above, clotting is induced by a non-metallic  
textured strand of the graft to fill the interstices  
between adjacent knitted loops within a reasonable time  
5 to form a patent covering over the wall portion of the  
graft.

Still other embodiments are within the following  
claims.

What is claimed is:

- 20 -

1. A tubular prosthesis comprising:  
a tubular wall portion of loosely interlocked knitted  
loops constructed to function within a body lumen, said  
loops being formed of co-knitted strand materials wherein  
5 a first strand material of said loops is a metal wire  
that structurally defines the tubular shape of said  
prosthesis and maintains said shape when positioned in  
said lumen and a second strand material of said loops,  
co-knitted with said metallic strand and comprising a  
10 predetermined substance selected to provide desired  
characteristics to the wall of said prosthesis.

2. A vascular graft prosthesis for bridging an  
aneurysm in an arterial lumen of the body comprising:  
a tubular wall portion of loosely interlocked  
15 knitted loops constructed to function within said  
arterial lumen, said loops being formed of co-knitted  
strand materials wherein a first strand material of said  
loops is a metal wire that structurally defines the  
tubular shape of said prosthesis and maintains said shape  
20 when positioned in said lumen and a second strand  
material of said loops, co-knitted with said metallic  
strand, comprises a predetermined non-metallic substance  
selected to provide desired characteristics to the wall  
of said prosthesis to enable it to perform its said  
25 function to effectively provide a patent covering over  
the structure of said graft.

3. The prosthesis of claim 1 or 2 including an  
anchoring end portion of knitted loops, knitted  
integrally with at least a portion of said co-knitted  
30 wall portion and formed of a strand material adapted to  
make contact with the wall of said body lumen to maintain  
the axial position of said prosthesis in said body lumen.

- 21 -

4. The prosthesis of claim 3 wherein said anchoring end portion is formed of contiguous loops of said first, metal strand material joined integrally with the said wall portion that includes said co-knit second  
5 strand.

5. The prosthesis of claim 1 or 2 wherein an anchoring end portion of said prosthesis is self-expanding, being formed of elastic metal strand capable of being reduced in radial size without plastic  
10 deformation and retaining self-restoring capability, whereby said end portion can be reduced to a relatively small size for introduction lengthwise into said lumen, and when freed can radially self-expand to tubular form to engage the wall of said lumen.

15 6. The prosthesis of claim 5 wherein said wall portion is expandable to desired size by means of an internal expanding force.

7. The prosthesis of claim 1 or 2 wherein said wall portion is expandable to a desired size by means of  
20 an internal expanding force.

8. The prosthesis of claim 7 wherein said first strand material of said wall portion is a plastically deformable metal, said wall portion being expandable to a desired size by application of an internal expanding  
25 force.

9. This prosthesis of claim 8 having an anchoring end portion formed of said plastically deformable metal and is knit integrally with said wall portion.

- 22 -

10. The prosthesis of claim 1 or 2 having an anchoring end portion formed of metal strand flared to a diameter greater than the wall portion.

5           11. The prosthesis of claim 1 or 2 including an anchoring portion at each of its axial ends.

12. The prosthesis of claim 1 or 2 wherein said first strand is selected from the group consisting of tantalum and nitinol.

10           13. The prosthesis of claim 12 wherein said second strand is selected from the group consisting of dacron, wool, nylon, polyethylene and teflon.

15           14. The prosthesis of claim 1 or 2 wherein the material of said second strand is textured to induce blood clotting.

15. The prosthesis of claim 14 wherein said prosthesis is sized for use as an aortic graft.

20           16. The prosthesis of claim 15 wherein said graft has a porosity of about 4000 ml/min or more at implantation.

17. The prosthesis of claim 1 or 2 wherein said wall portion includes a highly elastic strand and is self-expanding.

---

25           18. The prosthesis of claim 1 wherein said second strand is formed of a body fluid-dissolvable suture material.



- 23 -

19. The prosthesis of claim 1 or 2 wherein said second strand is an absorbing member that includes a drug.

20. The prosthesis of claim 1 or 2 wherein said 5 co-knit strands are in a parallel co-knit pattern.

21. A vascular prosthesis for use in an arterial lumen of the body comprising:

a tubular wall portion of loosely interlocked knitted loops constructed to function within said 10 arterial lumen, said loops being formed of parallel co-knitted strand materials wherein a first strand material of said loops is a metal wire that structurally defines the tubular shape of said prosthesis and maintains said shape when positioned in said lumen and a second strand 15 material of said loops, co-knitted with said metallic strand and comprising a textured textile strand substance selected to enhance patency characteristics of the wall of said prosthesis.

22. The prosthesis of claim 21 wherein said wall 20 portion is expandable to a desired size by means of an internal expanding force.

23. The prosthesis of claim 22 wherein said first strand material of said wall portion is a plastically deformable metal, said wall portion being expandable to a 25 desired size by application of an internal expanding force.

24. The prosthesis of claim 23 having an anchoring end portion formed of said plastically deformable metal and knit integrally with said wall 30 portion.

- 24 -

25. A tubular prosthesis comprising:  
a tubular wall portion of loosely interlocked  
knitted loops constructed to function within a body  
lumen, said loops being formed of multiple strand  
5 materials wherein a first strand material of said loops  
is a metal wire that structurally defines the tubular  
shape of said prosthesis and maintains said shape when  
positioned in said lumen and a second strand material of  
knitted loops, which comprises a predetermined substance  
10 selected to provide desired characteristics to the wall  
of said prosthesis.

26. The prosthesis of claim 25 wherein said first  
strand material and second strand material are  
continuously, single knitted to form regions of said  
15 tubular knit structure formed of said first material and  
regions of said knit structure formed of said second  
material.

27. The prosthesis of claim 26 wherein said first  
and second strand materials are alternately knitted to  
20 form successive alternating loop rows of said first and  
second material.

28. The prosthesis of claim 27 wherein said  
second strand is formed of a body fluid-dissolvable  
suture material.

25 29. The prosthesis of claim 28 wherein said  
second strand is an absorbing member that includes a  
drug.

30. The prosthesis of claim 25 or 27 wherein said  
second strand material is a metal.

- 25 -

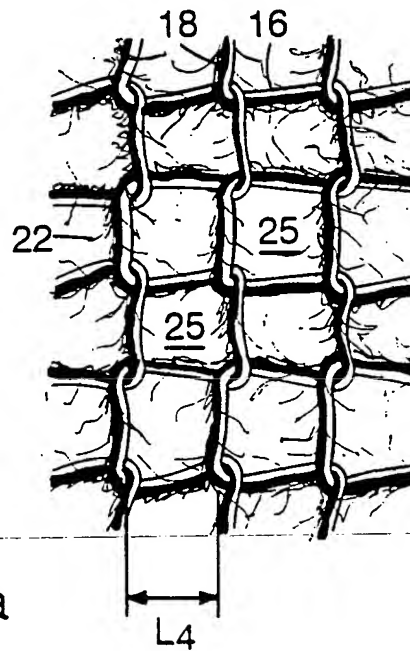
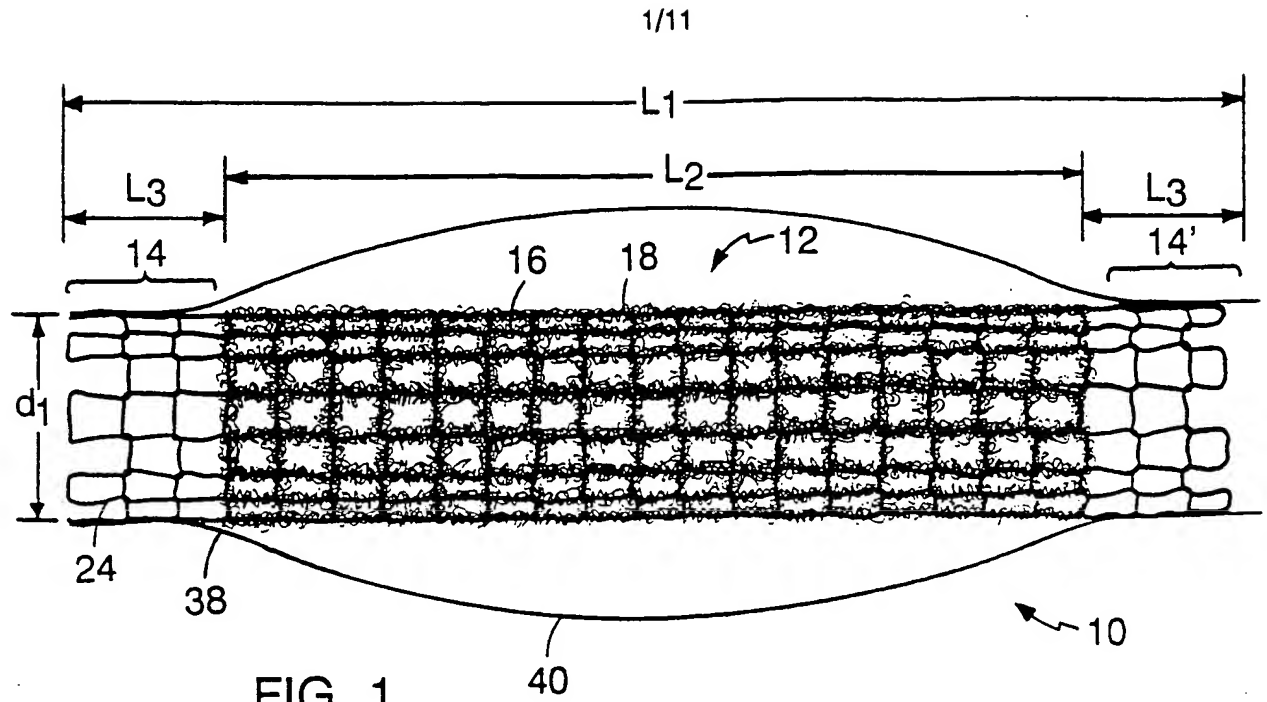
31. The prosthesis of claim 30 wherein said second strand material is a dense metal that enhances the radiopacity of said prosthesis.

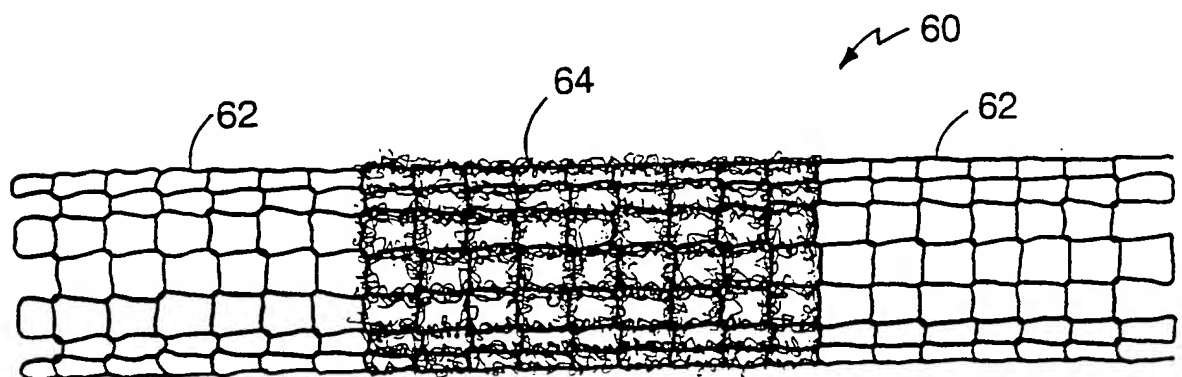
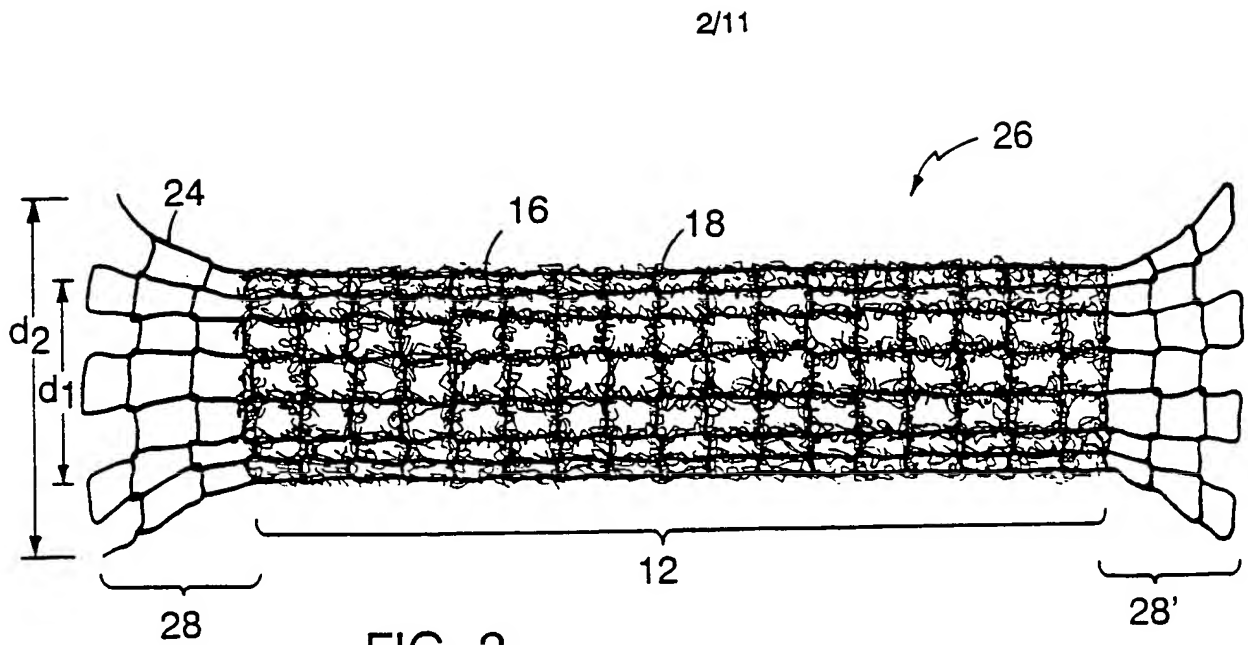
32. The prosthesis of claim 25 wherein said first  
5 and second strand materials are formed as separate knitted loop tubular structures and said second strand knitted loop structure extends coaxially with said first strand knitted loop structure, and extends over an end of said first strand knitted loop structure to form a cuff  
10 to secure said first knitted structure to said second knitted structure.

33. A tubular prosthesis comprising:  
a tubular wall portion of a loosely interlocked regular pattern of strands constructed to function within  
15 a body lumen, said pattern being formed of multiple strand materials wherein a first strand material of said pattern is a metal wire that structurally defines the tubular shape of said prosthesis and maintains said shape when positioned in said lumen and a second strand  
20 material of said pattern, integrated with said metallic strand as part of said pattern, which comprises a predetermined substance selected to provide desired characteristics to the wall of said prosthesis.

34. The tubular prosthesis of claim 33 wherein  
25 said pattern is formed by co-weaving or co-crocheting said strands.

35. The tubular prosthesis of claim 34 wherein said pattern is formed of multiple parallel strands.





3/11

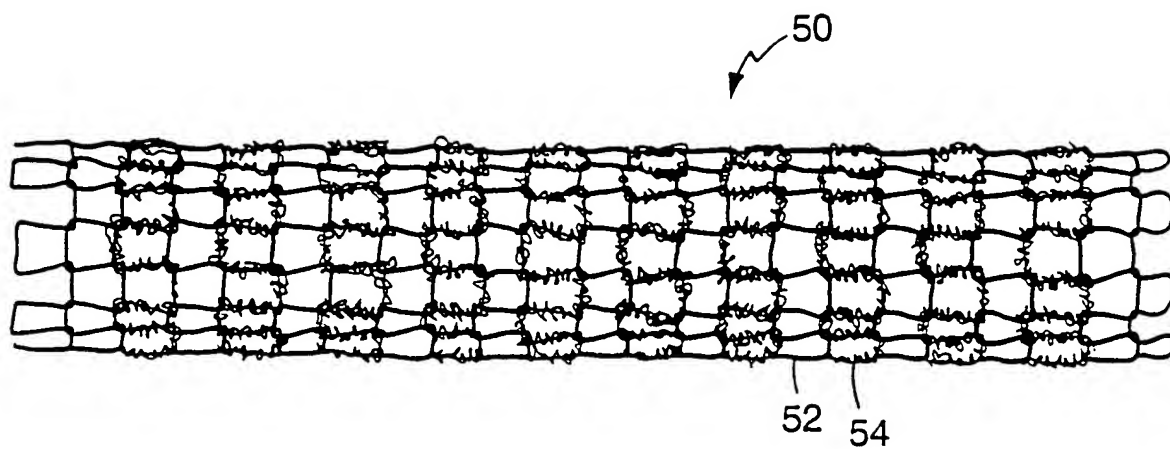


FIG. 3

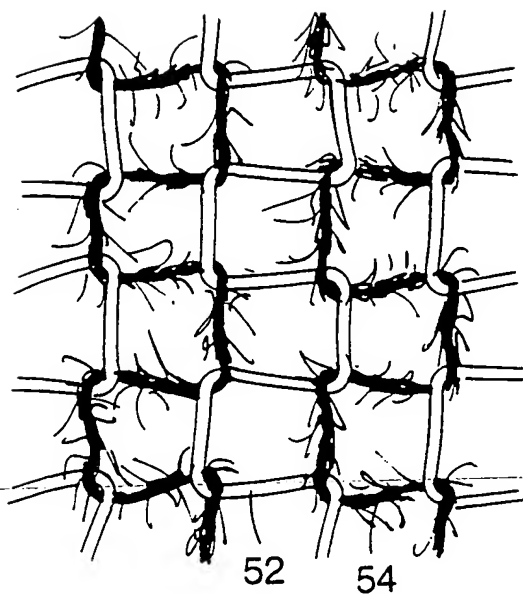


FIG. 3a

4/11

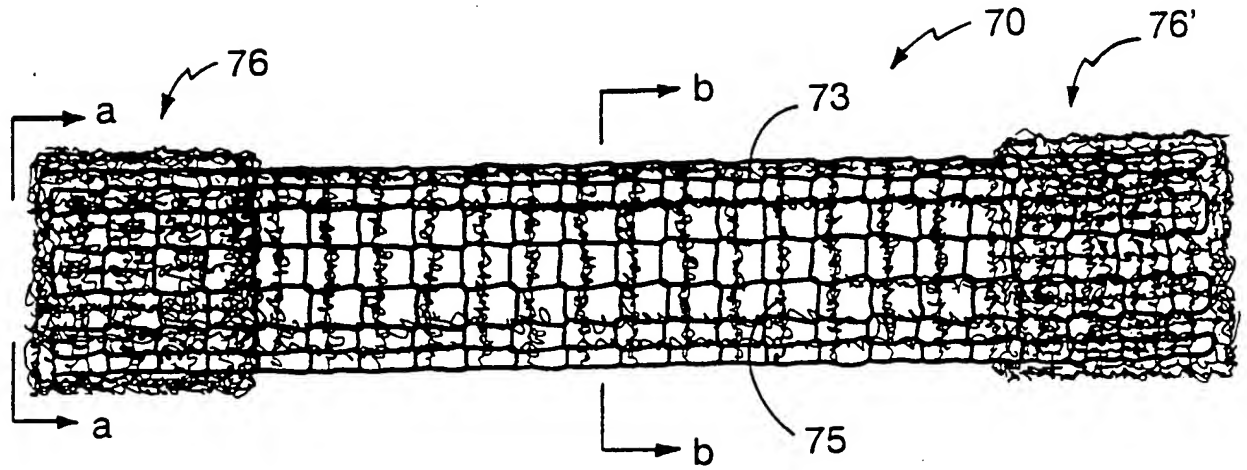


FIG. 5

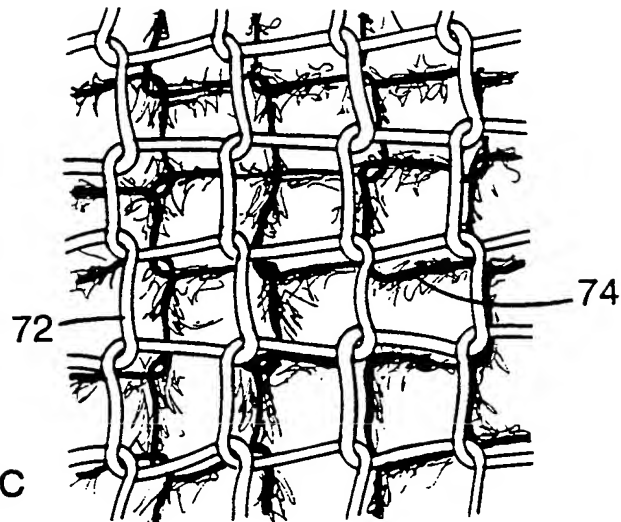


FIG. 5c

FIG. 5a

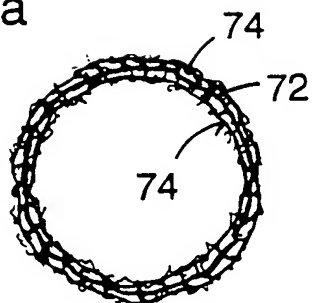
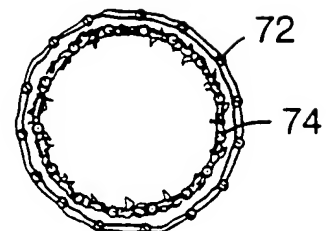
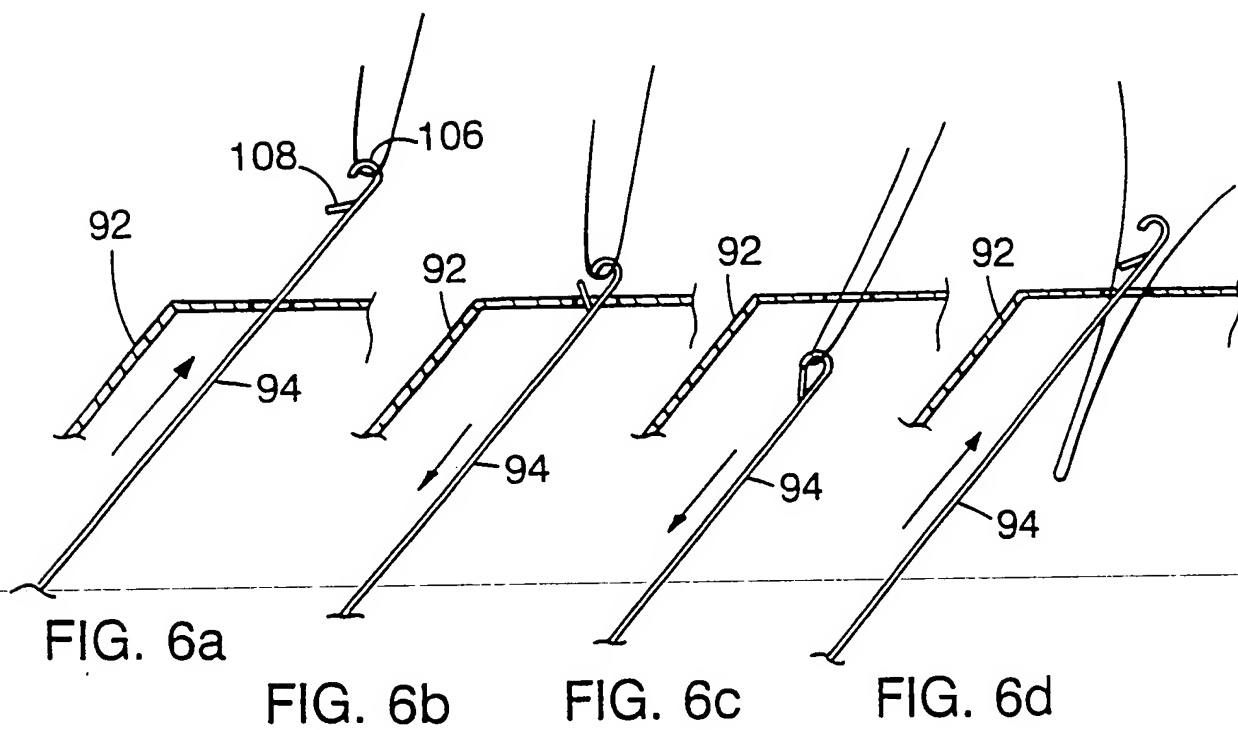
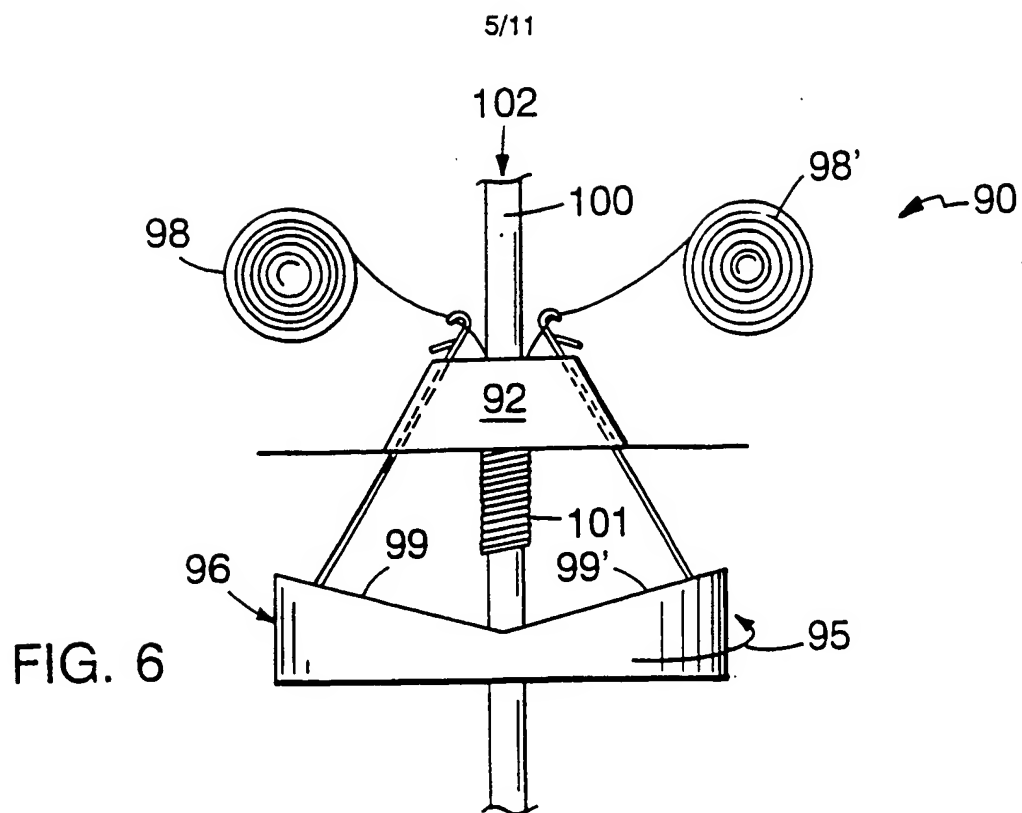


FIG. 5b







6/11

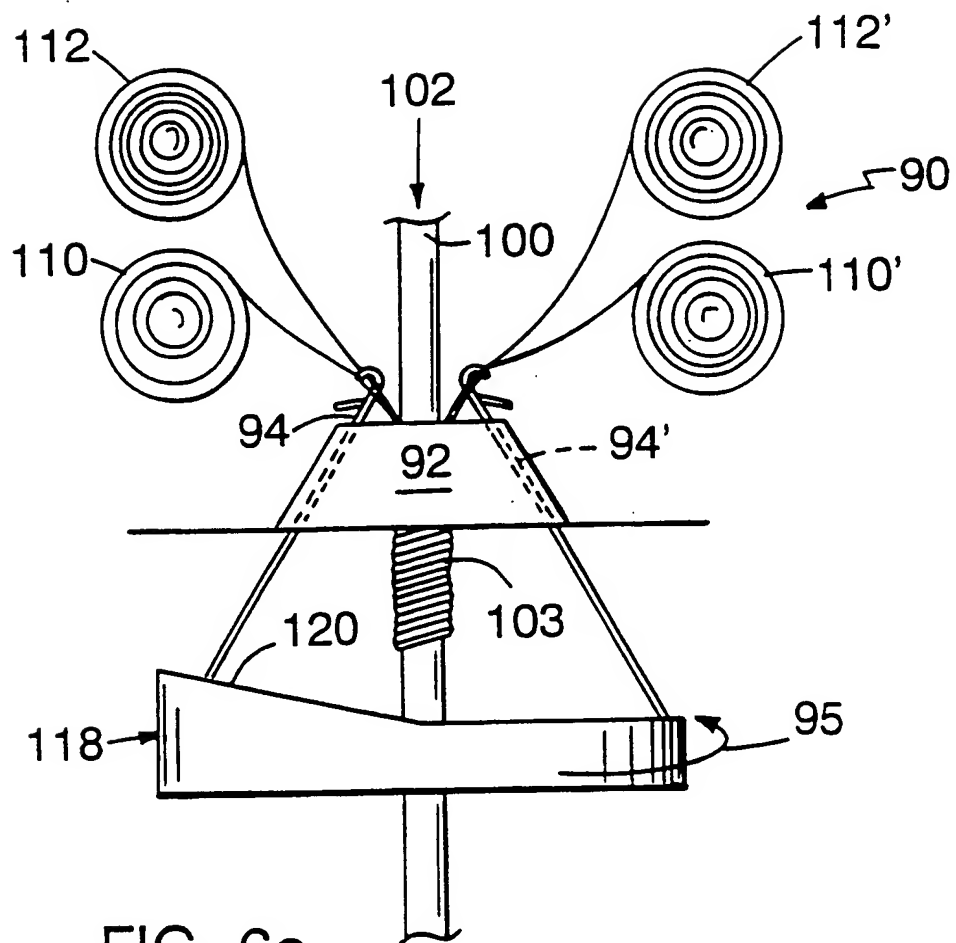


FIG. 6e

7/11

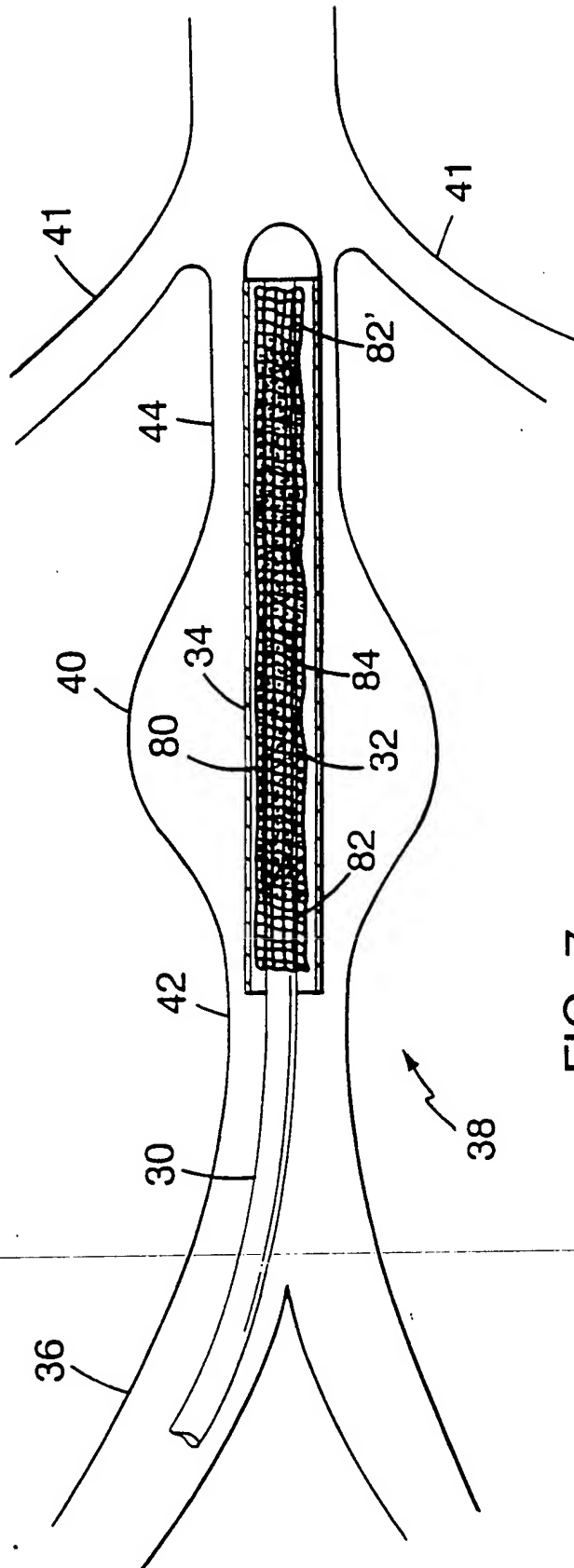


FIG. 7

8/11

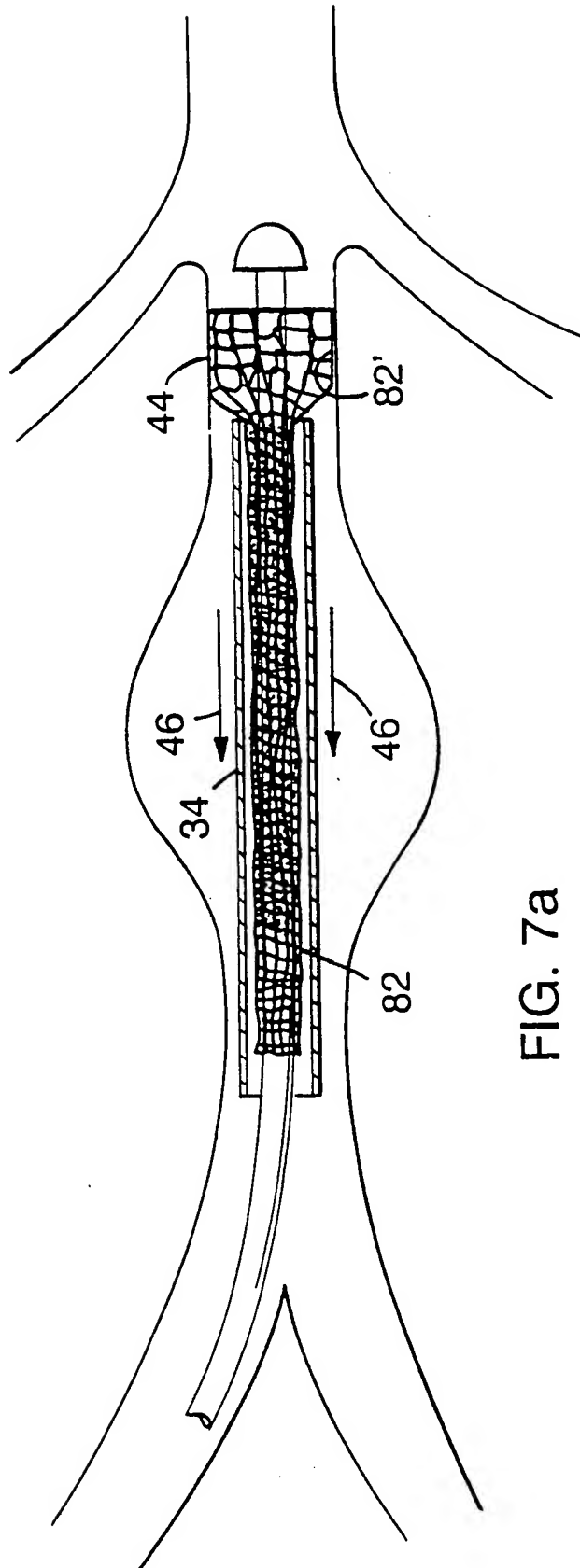


FIG. 7a

9/11

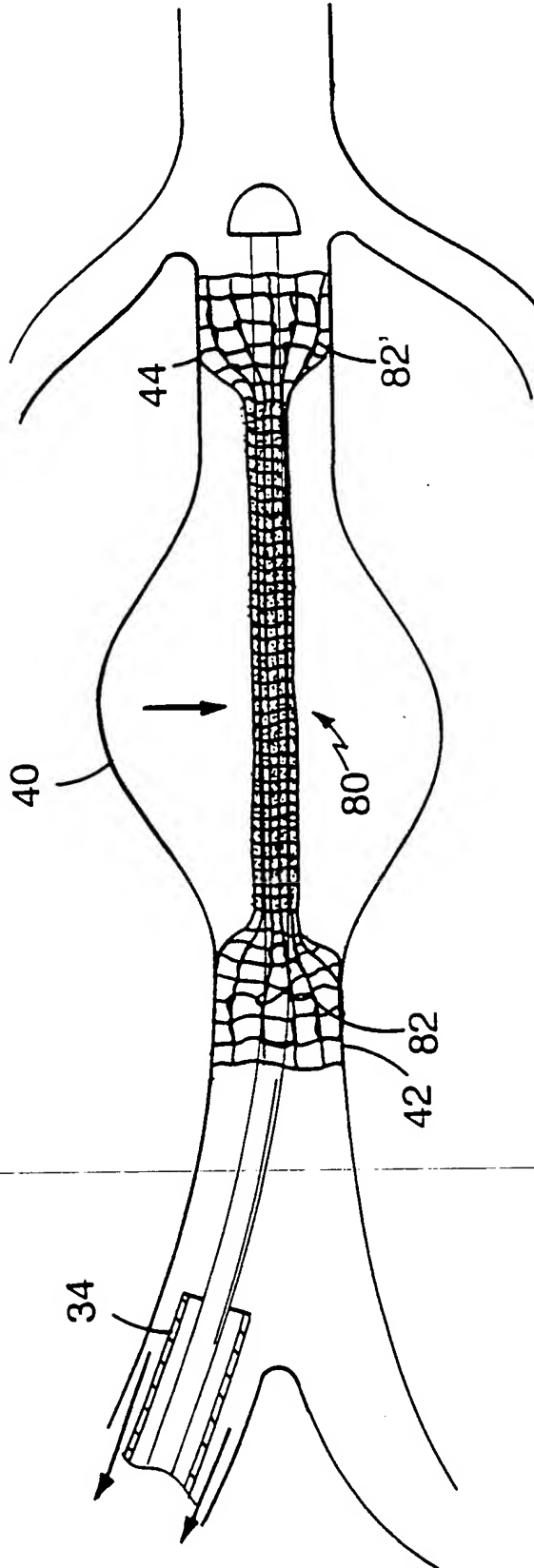


FIG. 7b

10/11

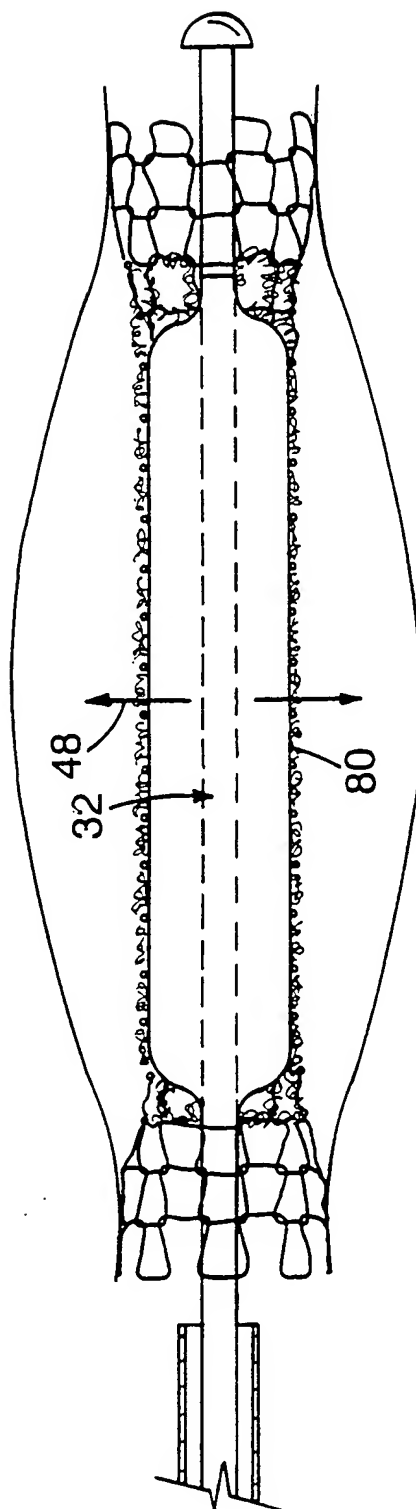


FIG. 7c

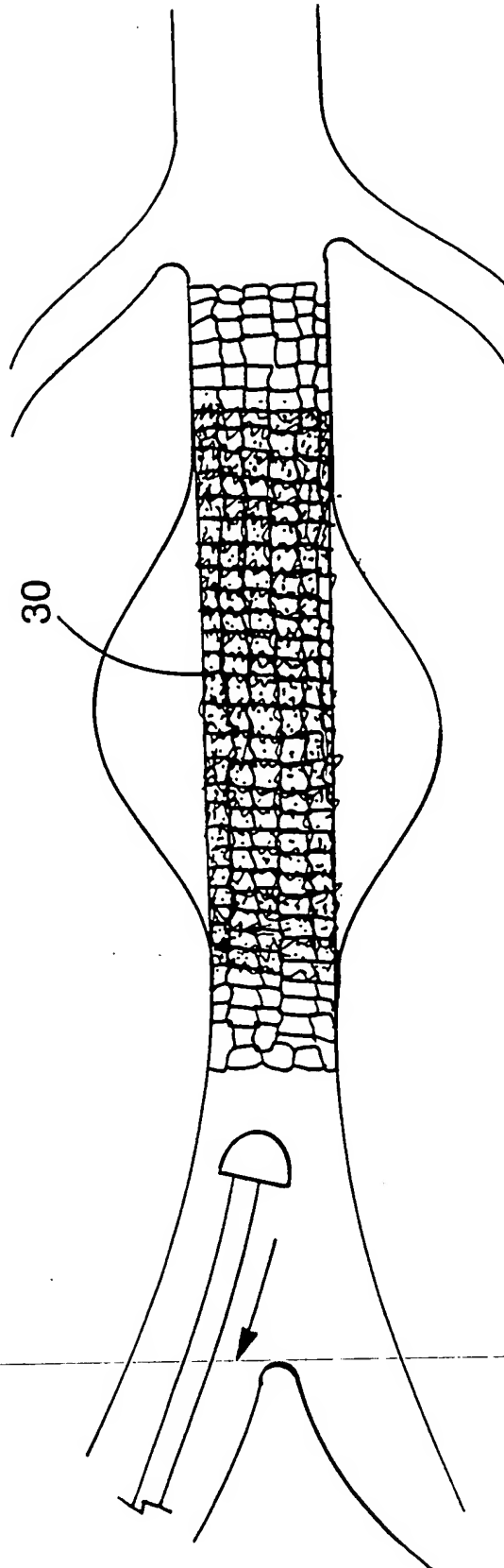


FIG. 7d

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/06529

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61F 2/04,2/06; A61M 29/00, 29/02

US CL :623/1,12; 606/194,195

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1,11,12;606/191,192,193, 606/194,195,196,197,198,199,200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US,A, 4,922,905 (STRECKER) ,08 MAY 1990, SEE COLUMN 3, LINES 20-53; COLUMN 8, LINES 39-45; COLUMN 9, LINES 22-32; COLUMN 6, LINES 44-60; COLUMN 4, LINES 24-26; AND , FIGURE 5.	1-11,20-25 26,27,30, 33-35 ----- 32
Y	US,A, 4,990,158 (KAPLAN ET AL), 05 FEBRUARY 1991, SEE THE ABSTRACT AND COLUMN 6, LINES 30-53	18,19,28 & 29
Y	EP, 0,364,787 (SCHATZ), 25 APRIL 1990, SEE COLUMN 7, LINES 22-27 AND COLUMN 6, LINES 29-32	12,17 & 31
Y, P	APPLICANT'S KNOWLEDGE (03 MAY 1993), SEE THE SUPPLEMENTAL INFORMATION DISCLOSURE	13-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means		
*P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

09 SEPTEMBER 1993

Date of mailing of the international search report

20 OCT 1993

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Authorized officer

DEBRA S. BRITTINGHAM

Facsimile No. NOT APPLICABLE

Telephone No. (703) 308-0858

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/06529

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP, 1,173,811 (LIEBIG), 10 DECEMBER 1969, SEE PAGE 6, LINES 71-90.	16